OK HAE 10/11/18

Violation	Discussion of Issues	Measures to Prevent Reoccurrence/Date Corrective Action Effected/Responsible party
The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (f) Diagnostic and therapeutic and/or (i) General (6).	1. Based on review of facility policies,, review of facility documentation, review of facility meeting minutes and interviews, the facility failed to ensure that the radiology data and/or issues were incorporated in the hospital-wide QAPI (Quality Assurance Performance Improvement) Committee. The finding includes: a. Review of facility documentation sent to the hospital by the DEEP (Department of Energy and Environmental Protection) dated 7/16/18 identified that the Hospital did not maintain accurate records of radiation exposure for all occupationally exposed radiation workers and monitoring records exceeded quarterly periodicity (reports for 5/2016 through March 2018 were reviewed). Review of radiation safety meeting minutes dated 5/19/16 identified that the DEEP had identified that too many dosimetry badges were being returned by staff unused. Review of Radiation Safety meeting minutes dated 8/15/16 noted emails were sent to individuals who did not return their badge and email messages were being sent to the Supervisors' of individuals who were not responding to the emails. Review of quarterly radiation safety meeting minutes dated 11/17/16 through 5/30/18 indicated, in part, that dosimetry badges were worn incorrectly and/or reported on as an on-going issue. Review of the Hospital QAPI meeting minutes dated 5/2016 through 8/2018 with the Compliance Officer on 9/7/18 at 11:38 AM identified that the QAPI committee convened on a monthly basis and radiation QA measures/ improvement guidelines were only discussed during the QAPI meeting dated 11/21/17. In addition, the data presented at the QAPI meeting dated 11/21/17 lacked documentation of the ongoing issue regarding the dosimetry badges. Interview with the Chief Quality Officer on 9/6/18 at 1:20 PM noted that the Department of Radiation reported to the Hospital Quality Committee in 2017 but, had no set reporting schedule. Interview with the Associate Vice President for Research on 9/6/18 at 2:08 PM indicated that he/she was not made aware of the ongoing dosimetry issues until 5/2017, and ongoing systemic issues should have been taking care of. Further interview identified that it	1a. **Action:** • QAPI will develop a set reporting schedule to include regular reporting of radiation exposure and other radiation concerns. • Reporting to Radiation Safety Committee will include ongoing dosimetry issues, including but not limited to, radiation exposure, records exceeding quarterly periodicity, return of radiation badges, dosimetry badges returned by staff unused, number of emails sent to staff and supervisors, dosimetry badges worn incorrectly, and results of audits/monitoring being completed to date. • Metrics to be reported to QAPI to include, but not be limited to, radiation exposure, records exceeding quarterly periodicity, return of radiation badges, dosimetry badges returned by staff unused, number of emails sent to staff and supervisors, dosimetry badges worn incorrectly, and results of audits/monitoring being completed to date. • Process is to be reviewed and revised as needed through programmatic review and by external auditors. **Compliance Monitor:** Audit of QAPI minutes for a minimum of three reports from radiation safety committee will be provided, analyzed, and where required, acted upon. Will continue auditing until reporting rate of 100% is achieved. The need for additional monitoring will be re-evaluated at that time. **Responsible Person:** Chief Quality Officer **Completion Date:** • QAPI will develop a set reporting schedule to include regular reporting of radiation exposure and other radiation concerns. – **10/01/18** • Reporting to Radiation Safety Committee will include

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	was an identifiable gap that the Radiation Department did not report regularly to the hospital- wide QAPI Committee. The Hospital QAPI Committee Charter identified a purpose to oversee QI initiatives in all areas of the Hospital functions and processes. The Charter further identified, in part, responsibilities to measure, analyze and track quality indicators and monitor performance improvement project status.	ongoing dosimetry issues, including but not limited to, radiation exposure, records exceeding quarterly periodicity, return of radiation badges, dosimetry badges returned by staff unused, number of emails sent to staff and supervisors, dosimetry badges worn incorrectly, and results of audits/monitoring being completed to date. – **10/16/18** • Metrics to be reported to QAPI to include, but not be limited to, radiation exposure, records exceeding quarterly periodicity, return of radiation badges, dosimetry badges returned by staff unused, number of emails sent to staff and supervisors, dosimetry badges worn incorrectly, and results of audits/monitoring being completed to date. – **10/16/18** • Process is to be reviewed and revised as needed through programmatic review and by external auditors. – **11/01/18**
The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (f) Diagnostic and therapeutic and/or (i) General (6).	2. Based on medical record review, review of facility radiation documentation, review of facility policies and interviews the facility failed to ensure that radiation policies were comprehensive. The finding includes: a. Review of facility documentation sent to the hospital by the DEEP (Department of Energy and Environmental Protection) dated 7/16/18 identified that the Hospital did not maintain accurate records of radiation exposure for all occupationally exposed radiation workers and monitoring records exceeded quarterly periodicity (reports for 5/2016 through March 2018 were reviewed). Review of radiation safety meeting minutes dated 5/19/16 identified that DEEP had identified that too many dosimetry badges were being returned by staff unused. Review of quarterly radiation safety meeting minutes dated 11/16/17, 2/27/18, 5/30/18 indicated, in part, dosimetry badges were worn incorrectly by physicians. On 9/6/18 and 9/7/18, a review of staff dosimetry reports for IR (interventional radiology) and the cardiac catheterization lab during the period of 5/1/18 through 7/31/18 identified that dosimetry badges, to include to include a minimum of a chest and collar badge per staff member were to be read on a monthly basis for all appropriate personnel. The review further identified that multiple staff failed to return badges and/or had negligible readings on badges returned. Observation on 9/6/18 at 11:00 AM noted that Medical	2a. **Action:** • Outside consultant has been retained to review policies and processes. • Policies to be reviewed, revised, and updated as required. • Establish a new process for documenting and tracking exposure of radiation. • Establish a new process for monitoring dosimetry badges unused by staff. • Provided education to staff required to wear dosimetry badges on properly wearing and returning dosimetry badges. **Compliance Monitor:** • Audit 50 staff members for properly wearing badges per month for a minimum of three months. Will continue observations until 50 consecutive observations with 100% compliance rate is achieved. The need for additional monitoring will be re-evaluated at that time. • Monitor all unused dosimetry badges returned against potential exposure. Will continue monitor until 100% compliance rate is achieved. The need for additional monitoring will be re-evaluated at that time.

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	Resident #1 was performing fluoroscopy procedures in the Fluoroscopy department and had donned a thyroid collar and apron for lead protection. The observation further indicated that although Medical Resident #1 had a dosimetry badge attached to his/her thyroid collar, he/she denied having a chest badge beneath the apron nor was a badge observed. Interview with Medical Resident #1 at this time identified that he/she was not aware if he/she was issued two badges and a second badge for Medical Resident #1 was not observed in the container of badges. Interview with the RSO (Radiation Safety Officer) on 9/6/18 identified that the dosimetry records included multiple negligible dosimetry badge readings (less than 2 millirem) and most likely reflected that badges were not being worn. Further interview with the RSO on 9/7/18 at 9:05 AM noted, in part that staff in the fluoroscopy room, cardiac catheterization lab and IR are required to wear 2 badges. The RSO further noted that one badge is to be worn on the outside of the collar and the other badge is to be worn under the apron at the chest or waist level. The hospital policy for personal radiation dosimetry identified that dosimeters must be placed on the front of the body from the waist to the upper chest and to call the Office of Radiation Safety for proper placement for other circumstances (i.e. an individual is wearing a lead apron). The policy did not provide direction for badge placement when the use of two dosimetry badges was required. The hospital job description for RSO identified a duty to develop, recommend, implement and monitor the Radiation Safety Program's standards, policies and procedures in accordance with regulations.	• Monitor all used dosimetry badges for unexpected negligible readings. Will continue monitor until 100% compliance rate is achieved. The need for additional monitoring will be re-evaluated at that time. **Responsible Person:** Radiation Safety Officer **Completion Date:** • Outside consultant has been retained to review policies and processes. – **10/01/18** • Policies to be reviewed, revised, and updated as required. – **11/01/18** • Establish a new process for documenting and tracking exposure of radiation. – **11/01/18** • Establish a new process for monitoring dosimetry badges unused by staff. – **11/01/18** • Provided education to staff required to wear dosimetry badges on properly wearing and returning dosimetry badges. – **09/21/18**
The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (f) Diagnostic and therapeutic and/or (i) General (6).	3. Based on a review of facility documentation, review of facility policies, review of facility observations and interviews, the facility failed to ensure that radiation exposure was appropriately monitored. The finding includes: a. A review of dosimetry reports from 5/2016 through March of 2018 identified a large number of discrepancies.	3a. **Action:** • Outside consultant has been retained to review policies

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	Each months dosimetry report showed many badges turned in a month or two late. In addition, badges that would show 'unused' for several months and then a higher than normal reading that might indicate a user had perhaps worn one badge for several months while the others were turned in unused. Review of radiation safety meeting minutes dated 5/19/16 identified that the DEEP had identified that too many dosimetry badges were being returned by staff unused. Review of quarterly radiation safety meeting minutes dated 11/16/17, 2/27/18, 5/30/18 indicated, in part, dosimetry badges were worn incorrectly by physicians. Review of staff dosimetry reports for IR (interventional radiology) and the cardiac catheterization lab during the period of 5/1/18 through 7/31/18 identified that dosimetry badges, to include a minimum of a chest and collar badge per staff member were to be read on a monthly basis for all appropriate personnel. Further review further identified that multiple staff failed to return badges and/or had negligible readings on badges returned. Review of credential files and/or facility training logs and/or the list of Medical Residents who worked in Interventional Radiology or the Cardiac Cath Lab indicated that 1 of 5 of these Medical Resident's (Medical Resident #2) lacked documentation for radiation safety training. Observation on 9/6/18 at 11:00 AM noted that Medical Resident #1 was performing fluoroscopy procedures in the Fluoroscopy department and had donned a thyroid collar and apron for lead protection. Further observation indicated that although Medical Resident #1 had a dosimetry badge attached to his/her thyroid collar, he/she denied having a chest badge beneath the apron nor was a badge observed. Interview with the RSO (Radiation Safety Officer) on 9/6/18 identified that the dosimetry records included multiple negligible dosimetry badge readings (less than 2 millirem) and most likely reflected that badges were not being worn. Interview with the Radiology Department's	and processes. • Provided education to staff required to wear dosimetry badges on properly wearing and returning dosimetry badges. • Review and revise radiation safety training program. • Establish a new process for reporting to supervisors and corrective action for employees for untimely or non-return of dosimetry badges. • Review and revise, as needed, potential corrective actions taken for non-return of badges. • Review and revise, as needed, resident- issued dosimetry badges and their return **Compliance Monitor:** • Monitor all dosimetry badges not returned or returned in an untimely manner. Will continue monitor until 100% timely return of all badges is achieved. The need for additional monitoring will be re-evaluated at that time. • Monitor all used dosimetry badges for unexpected negligible readings. Will continue monitor until 100% compliance rate is achieved. The need for additional monitoring will be re-evaluated at that time. • Monitor training completion for individuals who receive dosimetry badges for 100% completion within three months. The need for additional monitoring will be re-evaluated at that time. **Responsible Person:** Radiation Safety Officer **Completion Date:** • Outside consultant has been retained to review policies and processes. – **10/01/18** • Provided education to staff required to wear dosimetry badges on properly wearing and returning dosimetry badges. – **09/21/18** • Review and revise radiation safety training program. – **11/01/18** • Establish a new process for reporting to supervisors and corrective action for employees for untimely or non-return of dosimetry badges. – **10/16/18**

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	Administrative Assistant II on 9/6/18 at 12:00 PM noted that the RSO (Radiation Safety Officer) received all dosimetry badge collection reports. Further interview with the Radiology Department's Administrative Assistant II on 9/6/18 at 3:40 PM indicated that he/she did not have a method to track Medical Resident-issued dosimetry badges until recently (5/2018). The facility policy for personal radiation safety identified that all personnel who are working in the ionizing radiation area must wear Dosimetry. The policy noted that Dosimetry must be exchanged and returned by the end of the first week of each month. The hospital job description for RSO included responsibilities to monitor radiation safety programs and identify safety issues and initiate, recommend and/or provide corrective action and implementation of corrective action.	• Review and revise, as needed, potential corrective actions taken for non-return of badges. – **10/01/18** ✓ • Review and revise, as needed, resident- issued dosimetry badges and their return – **10/16/18**